

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

AQUESTIVE THERAPEUTICS, INC.,)	
)	
Plaintiff,)	
v.)	Civil Action No. 5:19-cv-00505-D
)	
BIODELIVERY SCIENCES)	
INTERNATIONAL, INC.,)	
)	
Defendant.)	
)	

**BIODELIVERY'S OBJECTIONS AND RESPONSES TO PLAINTIFF'S FIRST SET OF
REQUESTS FOR PRODUCTION PURSUANT TO RULE 34 (NOS. 1-12)**

Pursuant to Federal Rules of Civil Procedure 34, Defendant BioDelivery Sciences International, Inc. (“BioDelivery”) objects and responds to Plaintiff Aquestive Group, Inc.’s First Set of Requests for Production Pursuant to Rule 34 (Nos. 1-12) dated May 6, 2021 as follows:

GENERAL OBJECTIONS

BioDelivery incorporates each of the following General Objections into its responses to each of Aquestive’s Requests for Production (“Request” or “Requests”), whether or not each such General Objection is expressly cited in BioDelivery’s response to a specific Request.

1. BioDelivery will make a reasonable effort to respond to Aquestive’s Requests, as BioDelivery understands and interprets those Requests. If Aquestive subsequently asserts an interpretation of any Request that differs from BioDelivery’ interpretation, then BioDelivery reserves the right to supplement and amend its objections and responses.

2. BioDelivery objects to any Request to the extent that it is overly broad or unduly burdensome, or purports to impose upon BioDelivery any duty or obligation that is inconsistent

with or in excess of those obligations that are imposed by the Federal Rules of Civil Procedure, the Court's local rules, or any other applicable rule. In particular, BioDelivery objects to any Request to the extent that it calls for information that is not relevant to any party's claims or defenses and is not proportional to the needs of the case.

3. BioDelivery objects to any Request to the extent that it purports to impose a duty or obligation to search for information and documents beyond a reasonable search of its files where information responsive to the Requests would reasonably be expected to be found.

4. BioDelivery objects to any Request that seeks information protected from disclosure by the attorney-client privilege, the attorney work product doctrine, the joint defense or common interest doctrine, or any other applicable privilege or immunity. The inadvertent disclosure of information protected from disclosure by any privilege or doctrine shall not constitute a waiver by BioDelivery of such objections or protections. To the extent that a Request calls for documents containing privileged information, BioDelivery will produce a privilege log at an appropriate time and subject to Aquestive also providing a privilege log.

5. BioDelivery objects to any Request that seeks "any," "each," or "all" documents or things as overly broad and unduly burdensome, except to the extent that such Request seeks reasonably narrow, non-cumulative information. BioDelivery notes that most of the Requests are objectionable insofar as they, at a minimum, seek "all documents" or "all communications." Requests demanding the production of "all documents" are not proportional to the needs of this case. In response, and subject to its other objections, BioDelivery will produce responsive, representative documents that are non-cumulative, not protected from disclosure by the attorney-client privilege, work product doctrine, or any other applicable privilege or protection, and that

can be reasonably identified after a reasonable search of its files where documents responsive to such a Request would reasonably be expected to be found.

6. BioDelivery objects to any Request that is premature and/or conflicts with any schedule for disclosure or expert opinions entered by the Court or provided for by the local rules.

7. BioDelivery objects to Aquestive's "Definitions" and "Instructions" to the extent that they attempt to impose burdens and requirements upon BioDelivery that exceed or differ from the requirements of Rules 26 and 34 of the Federal Rules of Civil Procedure, the Court's local rules, or any other applicable rule or court order.

8. BioDelivery objects to Aquestive's definition of "infringe" and "infringement" to the extent that it purports to include infringement theories not alleged in this case.

9. BioDelivery objects to each Request to the extent that it seeks information that BioDelivery is under an obligation to a third party or a court order not to disclose, or is precluded from disclosing under legal obligations of any kind, including domestic or foreign privacy laws, U.S. agency regulations (e.g., regulations of the Department of Transportation and the TSA), and the like. BioDelivery will only produce responsive, non-privileged or otherwise protected information in accordance with any applicable legal standards and after receiving approval from the relevant third parties and in accordance with the Protective Order entered in the above-captioned litigation.

10. BioDelivery objects to the Requests to the extent they are not limited to a reasonable time period.

11. BioDelivery's responses and objections to the Requests are made without waiver and with preservation of the following rights and privileges:

- a. all questions as to competency, relevance, materiality, privilege, and admissibility of the responses and the subject matter thereof for any purpose and in any further proceeding in this lawsuit (including trial) and in any other action or matter;
- b. the right to object to the use of any such responses or the subject matter thereof, on any ground in any further proceeding in this lawsuit (including trial) and in any other action or matter;
- c. the right to object on any ground at any time to a Request or request for further responses; and
- d. the right at any time to review, correct, add to, supplement, or clarify any of the responses contained herein.

12. BioDelivery objects to the Instructions to the extent they seek to impose unilateral parameters concerning the collection and production of electronically stored information (ESI) beyond those required by the Federal Rules of Civil Procedure and any applicable local rule or court order.

13. All responses to the Requests are based on information presently known to BioDelivery after reasonable investigation. BioDelivery's objections as set forth herein are made without prejudice to BioDelivery's right to assert any additional or supplemental objections.

14. Any response in which BioDelivery agrees to produce responsive documents, whether or not made subject to objections, is not an admission or representation that any such document exists.

SPECIFIC RESPONSES AND OBJECTIONS TO
REQUESTS FOR PRODUCTION OF DOCUMENTS

REQUEST FOR PRODUCTION NO. 1:

All documents and things concerning Defendant's NDA, including the full and complete NDA, all documents and things submitted to the FDA in connection with Defendant's NDA, and supplements or amendments to Defendant's NDA, and all drafts of any of the above.

RESPONSE TO REQUEST NO. 1:

BioDelivery objects to this Request in purporting to seek production of information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it seeks highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in demanding the production of “[a]ll documents and things concerning Defendant's NDA...”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the

extent any are located after a reasonable search of its files and following entry of, and subject to the terms of, a protective order in this matter.

REQUEST FOR PRODUCTION NO. 2:

All documents and things considered or relied upon by Defendant in preparation of Defendant's NDA and any amendments or supplements thereof.

RESPONSE TO REQUEST NO. 2:

BioDelivery objects to this Request as seeking production of information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it seeks highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things considered or relied upon by Defendant in preparation of Defendant's NDA and any amendments or supplements thereof.” BioDelivery further objects to this Request as vague and ambiguous, in particular in demanding the production of “[a]ll documents and things considered or relied upon by Defendant”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.

REQUEST FOR PRODUCTION NO. 3:

All documents and things concerning any correspondence or communication relating to Defendant's NDA and/or BELBUCA, including any and all correspondence or communications to or from the FDA concerning Defendant's NDA, including any and all NDA amendments and supplements.

RESPONSE TO REQUEST NO. 3:

BioDelivery objects to this Request as seeking information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request to the extent that it seeks highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things concerning any correspondence or communicating relating to Defendant's NDA and/or BELBUCA...”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.

REQUEST FOR PRODUCTION NO. 4:

All documents and things reflecting all components of BELBUCA, including all active ingredients and inactive ingredients or excipients, and including an identification of the purpose of each component and the amount of each component contained in BELBUCA.

RESPONSE TO REQUEST NO. 4:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things reflecting all components of BELBUCA...”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.

REQUEST FOR PRODUCTION NO. 5:

All documents and things concerning the manufacture or testing of BELBUCA without regard to whether such testing was reported to the FDA.

RESPONSE TO REQUEST NO. 5:

BioDelivery objects to this Request as seeking information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this

case in purporting to demand the production of “[a]ll documents and things concerning the manufacture or testing of BELBUCA...” BioDelivery also objects to this Request as premature to the extent it purports to demand the production of expert discovery. BioDelivery further objects to this Request as seeking production of documents and things having no relevance to the claims and defenses in this matter, including in demanding production of documents and things reflecting “the manufacture … of BELBUCA.”

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 6:

All documents and things reflecting the procedures and processes used to manufacture BELBUCA, including, but not limited to, a description of all mixing, casting, drying, and coating steps, and a description of any changes to those manufacturing procedures and processes starting from the date the FDA approved BDSI’s NDA (i.e., October 23, 2015) through and including the present.

RESPONSE TO REQUEST NO. 6:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things reflecting the procedures and processes used to manufacture BELBUCA...” BioDelivery further objects to

this Request as seeking production of documents and things having no relevance to the claims and defenses in this matter, including in demanding production of documents and things reflecting “a description of all mixing, casting, … and coating steps.”

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 7:

All documents and things concerning the formulation and manufacture of Defendant’s BELBUCA Products, including any and all work done by Defendant or done at the Defendant’s instruction or for a Defendant’s benefit by others, to develop the formulation, the amounts and proportions of all ingredients and materials used in the formulation, and all associated processing methods and manufacturing steps.

RESPONSE TO REQUEST NO. 7:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things concerning the formulation and manufacture of Defendant’s BELBUCA Products...” BioDelivery further objects to this Request as seeking production of documents and things having no relevance to the

claims and defenses in this matter, including in demanding production of documents and things reflecting “all associated processing methods and manufacturing steps.”

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 8:

All documents and things concerning the drying process for Defendant’s BELBUCA products that Defendant considered, tested, evaluated, or proposed for submission to the FDA, or submitted to the FDA.

RESPONSE TO REQUEST NO. 8:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things concerning the drying process for Defendant’s BELBUCA products that Defendant considered ...”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.

REQUEST FOR PRODUCTION NO. 9:

All documents and things concerning testing, evaluation, or measurements conducted by or on behalf of BDSI related to the amount and distribution of active ingredients in BELBUCA, including, but not limited to testing, evaluations, or measurements of the amount and distribution of active ingredients in an individual dosage unit and/or the variation of the amount and distribution of active ingredients between individual dosage units.

RESPONSE TO REQUEST NO. 9:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things concerning testing, evaluation, or measurements conducted by or on behalf of BDSI related to the amount and distribution of active ingredients in BELBUCA...” BioDelivery further objects to this Request as premature to the extent it purports to demand production of expert discovery.

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.

REQUEST FOR PRODUCTION NO. 10:

All documents and things concerning methods, calculations, and analyses related to determining the amount and distribution of active ingredients, in any pharmaceutical film product created during the development of, or tested for the purpose of developing, Defendant's BELBUCA Products.

RESPONSE TO REQUEST NO. 10:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things concerning methods, calculations, and analyses related to determining the amount and distribution of active ingredients, in any pharmaceutical film product created during the development of, or tested for the purpose of developing, Defendant's BELBUCA Products.” BioDelivery also objects to this Request as vague and ambiguous in seeking production of “[a]ll documents and things concerning ... any pharmaceutical film product created during the development of, or tested for the purpose of developing, Defendants' BELBUCA Products.”

Subject to these objections and the foregoing General Objections, BioDelivery will produce responsive, non-privileged documents in its possession, custody, and control to the

extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.

REQUEST FOR PRODUCTION NO. 11:

All documents and things related to or referring to process flow specifications performed or investigated during production or development of Defendant's BELBUCA Products, including ingredients, amounts, mixing, casting, drying steps and detailed diagrams and/or photographs of the apparatuses used in each step.

RESPONSE TO REQUEST NO. 11:

BioDelivery objects to this Request to the extent it seeks information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as seeking highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things related to or referring to process flow specifications performed or investigated during production or development of Defendants' BELBUCA Products...” BioDelivery further objects to this Request as demanding production of information irrelevant to the claims and defenses in this matter, including in demanding production of documents and things “related to or referring to ... amounts, mixing, casting, ... steps and detailed diagrams and/or photographs of the apparatuses used in each step.”

Subject to the foregoing General and specific objections, BioDelivery responds that it is willing to meet and confer to narrow the scope of this Request.

REQUEST FOR PRODUCTION NO. 12:

All documents and things relating to Defendant's assertions that Defendant's BELBUCA Product does not infringe and will not infringe the patents-in-suit, including all such information that Defendant contend support those positions or which tends to undermine or contradict such contentions.

RESPONSE TO REQUEST NO. 12:

BioDelivery objects to this Request as seeking the production of information that is protected from disclosure by the attorney-client privilege, joint defense or common interest doctrine, the attorney work product doctrine, and/or other applicable privilege, doctrine, or immunity. Further, BioDelivery objects to this Request as untimely at least because Aquestive has not served its infringement contentions as provided under Local Patent Rule 303.1. Further, BioDelivery objects to this Request as seeking the production of highly confidential information of BioDelivery prior to the entry of an agreed-upon protective order. BioDelivery also objects to this Request as vastly overbroad, unduly burdensome, and not proportional to the needs of this case in purporting to demand the production of “[a]ll documents and things relating to Defendant's assertions that Defendant's BELBUCA Product does not infringe or will not infringe the patents-in-suit...” BioDelivery further objects to this Request as premature in purporting to demand production of expert discovery. BioDelivery also objects to this Interrogatory as nonsensical in seeking production of information regarding the “patents-in-suit.”

Subject to these objections and the foregoing General Objections, and to the extent BioDelivery can understand this Request, after Aquestive discloses adequate infringement contentions—if it does so—BioDelivery will produce responsive, non-privileged documents in

its possession, custody, and control to the extent any are located after a reasonable search and following entry of, and subject to the terms of, a protective order in this matter.

Dated: June 7, 2021

OF COUNSEL:

/s/ Kia L. Freeman

Kia L. Freeman
Wyley S. Proctor
Thomas F. Foley
McCARTER & ENGLISH LLP
265 Franklin Street
Boston, Massachusetts 02110
Telephone: (617) 449-6500
kfreeman@mccarter.com
wproctor@mccarter.com
tfoley@mccarter.com

*Attorneys for Defendant
BioDelivery Sciences International, Inc.*

/s/ Peter D. Siddoway

Lynne A. Borchers
NC State Bar No. 32386
Peter D. Siddoway
NC State Bar No. 45647
SAGE PATENT GROUP, PLLC
4120 Main at North Hills St., Suite 230
Raleigh, North Carolina 27609
Telephone: (984) 219-3358
Facsimile: (984) 538-0416
lborchers@sagepat.com
psiddoway@sagepat.com

*Local Civil Rule 83.1(d)
Counsel for Defendant
BioDelivery Sciences International, Inc.*

CERTIFICATE OF SERVICE

I, certify that on June 7, 2021, I served this document on Plaintiff Aquestive Therapeutics, Inc., by emailing this document to Aquestive's counsel of record at the following e-mail addresses:

James F. Hibey at jhibey@steptoe.com
Jamie Lucia at jlucia@steptoe.com
John L Abramic at jabramic@steptoe.com
Anna M. Targowska at atargowska@steptoe.com
Joseph A. Schouten at jas@wardandsmith.com
E. Bradley Evans at ebe@wardandsmith.com
SJAquestiveNC@Steptoe.com

/s/ Peter D. Siddoway

Peter D. Siddoway
NC State Bar No. 45647
SAGE PATENT GROUP, PLLC
4120 Main at North Hills St., Suite 230
Raleigh, North Carolina 27609
Telephone: (984) 219-3358
Facsimile: (984) 538-0416
psiddoway@sagepat.com